



September 17, 1999

**MEMORANDUM**

**To:** Administrators, Renal Dialysis Facilities

**From:** Jerry L. Paul, Director  
Health Licensing Section *Jerry L. Paul*

**Subject:** Conditions Allowing a Provider-wide Exception to the Requirements of Section 409.D of Regulation 61-97, Standards for Licensing Renal Dialysis Facilities

**NOTE:** This memorandum replaces the exception to the standards regarding hepatitis testing communicated to renal dialysis facilities in a memorandum from Health Licensing dated November 3, 1994.

The section in the regulations mentioned above requires certain procedures to be followed regarding hepatitis testing.

It has been determined that the need to adhere to the procedure outlined in the regulations may be excessively restrictive. In the interest of establishing reasonable standards which can be met by providers and yet do not compromise the health, safety, and well-being of patients cared for in the above facilities, it has been determined that alternative standards will be considered as acceptable.

All renal dialysis facilities will be required to meet the standard outlined in R61-97, Section 409.D, **or, as an alternative:**

1. For employees:

a. Check medical records or conduct a baseline test for HBsAg (Hepatitis B surface antigen) and HBsAb (Hepatitis B surface antibodies).

(1) If HBsAb is (+), the employee is considered naturally immune, either from natural infection or vaccination, and needs no further testing

(2) If HBsAg is (+), the employee is likely a chronic HBV (Hepatitis B Virus) carrier, and must be re-checked every six months for two years.

(3) If HBsAb is (-), the employee shall be offered the Hepatitis B vaccine series (per CDC guidelines). If the Employee declines, test for HBsAg quarterly.

b. One to two months after completion of this primary vaccine series, re-check HBsAb.

(1) If HBsAb is (-), thereby indicating initial non-responder, recommend a second three- dose Hepatitis B vaccine series and re-check in one to two months after completion.

(2) If HBsAb is again (-), the employee is classified as a "known vaccine non-responder" and need not be thereafter tested for HBsAb, but must be tested for HbsAg quarterly.

c. If HBsAb is (+) after either the primary or second series, the employee is classified as a "known vaccine responder," is considered immune to Hepatitis B infection, and needs no further testing.

d. In the event of an occupational blood-borne pathogen exposure, a employee who is HBsAb (-) must be managed as a "known non-responder" (per CDC guidelines).

e. If a test for HBcAb indicates (+) = natural infection; (-) = no evidence of viral infection. (A (+) core Ab does not determine immunity)

2. For patients:

a. Conduct a baseline check for HBsAg and HBsAb

(1) If HBsAb is (+), the patient is considered naturally immune and needs no further testing;

(2) If HBsAg is (+), the patient is likely a chronic HBV (Hepatitis B Virus) carrier, and must be rechecked every six months for two years.

(3) If both HBsAg and HBsAb are (-), the patient shall be offered the Hepatitis B vaccine series (per CDC guidelines). If the patient declines, test for HBsAg quarterly.

b. One to two months after completion of this primary vaccine series, re-check HBsAb.

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(1) If HBsAb is (-), indicating an initial non-responder, recommend second three-dose Hepatitis B vaccine series and recheck in one to two months after completion.

(2) If HBsAb then again is (-), the patient is classified as a "known non-responder" and must be thereafter tested for HBsAg quarterly.

c. If HBsAb is (+) after either primary or second series, the patient is classified as a "known vaccine responder," is considered immune to Hepatitis B infection, and needs no further testing.

d. If a test for HBcAb indicates (+) = natural infection; ( - ) = no evidence of natural infection.

This exception apply to any renal dialysis facility licensed by the Department. It relates solely to SC licensing standards. Any adverse condition(s) that may be related to this exception may result in revocation of the exception by the Department.

If there are any questions, you may call George Moore or Rob Lawyer at (803) 737-7370.

JPL/JML

cc: Alice Truluck, Customer Service Liaison  
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Licensed hospitals and institutional general infirmaries